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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Assaf Govari

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10/31/2008

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NEW BRUNSWICK, NJ 08933-7003

EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

10/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/882,126	Applicant(s) GOVARI, ASSAF	
	Examiner Fangemonique Smith	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/28/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Remarks filed on August 11, 2008. Examiner acknowledges the amendment of claim 4. Claims 1-21 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5 and 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (U.S. Patent Number 5,755,715) in view of Maynard (U.S. Patent Number 5,405,337) and in further in view of More (U.S. Patent Number 6,334,093).

In regard to claims 1-5 and 9-15, Stern et al. disclose a tissue heating and ablation system which upon use employs an energy emitting electrode to heat tissue. The system upon use further includes a method for measuring temperature at a site of interest within a patient comprising steps of providing a medical device having a position sensor and placing the medical device within the patient, positioning the position sensor at the site of interest (col. 1, lines 48-67; col. 2, lines 1-49). Stern et al. disclose thermal mapping techniques employed to determine temperature curve coordinates. Stern et al. disclose upon use of the system a voltage is measured at the site of interest and a temperature measurement is taken (col. 5, lines 10-64). Stern et al. disclose the temperature is determined based on an algorithm which includes a resistance value obtained (col.

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5; col. 6, lines 1-35). Upon use, the Stern et al. device further includes generating an externally applied field at the patient wherein the frequency of the generator signal is different than the temperature measurement signal. As described, Stern et al. disclose the features of the Applicant's invention as described above. Although Stern et al. discloses thermal mapping and techniques which indicate position of the medical device, Stern et al. do not specifically disclose the use of a position sensor. Maynard discloses a film for use with a steerable device to allow the steerable device precise and dexterous maneuvering in a three dimensional space. Maynard discloses the device having positional sensors and sensors for measuring environmental parameters (col. 8, lines 3-25). An environmental parameter measured by the Maynard device includes temperature. The Maynard reference further teaches the application of a magnetic field upon use of the device. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue heating and ablation system, similar to that disclosed by Stern et al., to include a film to be used with a steerable catheter, similar to that disclosed by Maynard, to provide information regarding the location of the device while enabling the device to be accurately positioned at the target site. The combined references of Stern et al. and Maynard disclose features of Applicant's invention as described above. The combined references do not disclose providing a resistance drift factor to the resistance value. More discloses a method and apparatus for measurement of temperature differences. The More patent discloses a device which accurately resolves extremely small differences in electrical signals by incorporating a drift compensation factor upon measurement of differences in a physical variable such as temperature. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue heating and ablation

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system, similar to that disclosed by the combined references of Stern et al. and Maynard, to include a resistance drift factor, similar to that disclosed by More, to improve the accuracy of the results obtained while maintaining the functionality of the device.

4. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (U.S. Patent Number 6,241,724) as modified by Maynard (U.S. Patent Number 5,405,337) in view of More (U.S. Patent Number 6,334,093) and in further view of Acker (U.S. Patent Number 5,833,608).

In regard to claims 6-8, the combined references of Stern et al., Maynard, and More disclose a method for measuring temperature at a site within a patient during a medical procedure which includes the features of the Applicant's invention as described above. The combination further describes the medical device being capable of determining a temperature value and temperature sensitivity based on the resistance value. The combined references further disclose performing an ablation procedure at the site with the medical device, however the combined references fail to specifically disclose the use of an AC generator signal to apply a magnetic field to the patient. Acker discloses a magnetic positioning and orientation determining system which uses magnetic fields to deduct the position and orientation of a probe. The system of the Acker patent is used to perform ablation procedures. The device includes a signal generator, which delivers an AC signal to the distal tip of the device. Operation of the device further includes transforming the AC signal into a DC signal upon utilizing a synchronous detector. The generator signal of the Acker device is capable of operating at 3KHz with the temperature measurement signal at 4Hz. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to include an AC generator and synchronous detector system, similar to that

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disclosed by Acker, to deliver an AC signal to a medical device, similar to the device described in the combined references of Stern et al., Maynard, and More, as a way to provide a means for superimposing the probe onto a separately acquired image to display the position and orientation of the probe with respect to the patient.

5. Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stern et al. (U.S. Patent Number 6,241,724)) as modified by Maynard (U.S. Patent Number 5,405,337) in view of More (U.S. Patent Number 6,334,093) and in further view of Douglass et al. (U.S. Patent Number 5,638,418).

In regard to claims 16-21, the combined references of Stern et al., Maynard, and More disclose a method for measuring temperature at a site within a patient during a medical procedure. The combination does not specifically disclose providing a sensitivity drift factor to the temperature value when executing the algorithm. Douglass et al. disclose a system and method that is used to detect temperature. The method includes including an error term to simulate possible drift of resistance values. The system of the Douglass et al. patent uses the resistance drift coefficient during its processing step, which is stored by a memory device of the system. Douglass et al. further disclose a temperature coefficient introduced to adjust the temperature measurement according to the temperature sensitivity of the device in operation. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to apply correction factors, similar to those disclosed by Douglass et al., to an algorithm used to measure temperature similar to the one used by the combined references of Stern et al., Maynard, and More, in order to improve the accuracy of the calculated measurement and reduce sources of variability.

Response to Arguments

6. Applicant argues the prior art references do not teach a system and method which uses a location system capable of determining position and/or orientation coordinates of a position sensor located on the medical device. Examiner submits, the Stern et al. reference does not specifically disclose a position sensor. However the Stern et al. device discloses a sensor whose position is identified through the thermal mapping techniques. Although Examiner believes the Stern et al. device is capable of determining position of the device, the Examiner has modified the rejection above since the Stern et al. device failed to specifically disclose the use of a position sensor. As described above, Examiner has included a reference which teaches the use of both temperature and position sensors specifically. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FANGEMONIQUE SMITH whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736